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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,688	11/25/2003	Gad Lavie	LAVIE7A	3051

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,688	LAVIE, GAD	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-13 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for regulating or reducing the phototoxicity by using certain effector photosensitizing and certain quenching photosensitizer molecule, does not reasonably provide enablement for reducing, regulating or preventing phototoxicity using all effector photosensitizer and all quenching photosensitizer molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method for regulating, reducing or preventing the localized phototoxicity of an effctor photosensitizer molecule during photodynamic therapy by using a quenching photosensitizer molecule prior to administering an effctor photosensitizing molecule.

2) The state of the prior art:

The prior art does not recognize that all effector photosensitizing agents have the same degree of phototoxicity in photodynamic therapy or all quenching

photosensitizing agents have the same activity in reducing or preventing photosensitizing agents used by an effector photosensitizing agent. Applicant on page 3 of the specification admits that the sole photosensitizer for clinical use in photodynamic therapy of AMD is vertiporfin. Applicant on the same also admits that the major disadvantage of this treatment is attributed to the pharmacokinetics properties of vertiporfin, where there is a strict time-related limitation. Such statements indicate that not all effector molecules have the same pharmacokinetics as vertiporfin and not all effectors can damage the surrounding tissues during the photodynamic therapy. Applicant also on page 13 of the specification admits that the absorption spectra of certain range, lipophilicidity that attributes to a specific alpha-half life with a specific elimination half life and specific red/ox potentials enable a quenching agent to be effective in reduction of damage by an effector agent. Such statement teaches away from the effectiveness of all quenching agents in the reducing the damage caused by an effector photosentisizer during photodynamic therapy.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are very broad and encompass the use of any effector photosentisizing agent and any quenching photosensitizing agent for reducing, regulating and preventing phototoxicity during photodynamic therapy.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for regulating and reducing the localized phototoxicity of the effector photosensitizer vertiporfin using hypericin as a quenching molecule. However, the specification provides no guidance, to enable one of ordinary skilled in the art to use the invention commensurate in scope with the claims. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: " It is well settled that in cases involving chemical and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired results". Applicant's specification does not set forth a representative number of examples to demonstrate regulating, reducing or preventing of the phototoxicity of an effector photosensitizer molecule using a quenching photosensitizer agent.

7) The presence or absence of working examples:

The examples in applicant's specification are drawn to the combination of one effector photosensitizer molecule and one quenching photosensitizing molecule for reducing photototoxicy associated with photodynamic therapy. Such examples are not commensurate in scope with the claimed language. Furthermore, there are no examples to demonstrate the prevention of phototoxicity during photodynamic therapy.

8) The quantity of experimentation necessary:

Since compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all quenching photosensitizer molecules, which are capable of regulating, reducing or preventing phototoxicity caused by all photosensitizer molecules.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C.103 (a) as being unpatentable over the Medline Abstract 10755329 and Margolis-Nunno et al (6,087,141).

The Medline abstract teaches the use of verteprofin in photodynamic therapy for the treatment of age related macular degeneration. See the entire abstract. The above reference differs from the claimed invention in the use of a quenching agent in order to reduce the phototoxicity of an effector photosensitizer molecule. Margolis-Nunno et al. Teach the addition of a quenching agent such as hypericin to an effector molecule being used as antiviral agent in blood, for killing viruses without affecting the surrounding functional cells. See column 3, lines27-35, column 5, lines 38-53. The above reference on column 4, line 54, also teach that the invention can be employed to treat the product of the composition containing non-blood normal or cancerous cells or the product of gene splicing. It would have been obvious to a person skilled in the art to incorporate a

quenching agent into the teaching of the primary reference, considering that Margolis et al. teach the use of a quenching agent in photodynamic therapy for the reduction of the phototoxicity of the effector photosensitizing molecule to the functional tissues and cells is old and well known.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of photodynamic therapy for the treatment of the claimed disorders and the other relates to the addition of a quenching agent such as hypericin to photodynamic therapy in order to reduce the phototoxicity of the effector molecule. The use of the quencher compounds for the reduction of the phototoxicity of the surrounding tissues would have been obvious to a person skilled in the art, considering that Margolis et al. in column 4, lines 54-56 teach that the use of the quenching agents is not only for the protection of blood cells but it can also be used for non-blood or cancerous cells. The determination of optimum proportions or amounts is considered to be within the skill of the artisan in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-13 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

SUPERVISORY PATENT EXAMINER
GROUP 1200